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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,895	12/14/2005	Peter Geisser	GIL-15940	5889

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RANKIN, HILL, PORTER & CLARK, LLP
925 EUCLID AVENUE, SUITE 700
CLEVELAND, OH 44115-1405

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,895	GEISSER ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/06.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 20070929.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-17 are pending in this application.

Applicant is requested to insert the following as the first paragraph of the specification to recite complete application information --- This application is a 371 of PCT/EP03/11596, filed on October 20, 2003, which [fill in relevant info] --- .

A misspelling is noted in claim 5: "maltrodextrin."

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 provide for the use of iron carbohydrate complexes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Because "use" claims do not belong to a statutory recognized category of invention, they cannot be further examined on the merits. Further, applicant is hereby *given advance notice* that should these claims be resubmitted as method of treating or method of providing prophylaxis, they will be deemed to lack unity of invention and the remaining current claims will be deemed to have been elected by original presentation. Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The "contribution over the prior art" is considered with respect to novelty and inventive step. See PCT Rule 13.1 and 13.2; see also MPEP 1850. As will be established hereinbelow, the iron carbohydrate complex of claim 1 lacks novelty, so there is no contribution over the prior art made by a corresponding special technical feature.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by HCAPLUS abstract 1960:117732.

HCAPLUS abstract 1960:117732 explicitly discloses ferric D-glucuronate. Solution obtained from an ion exchange column is concentrated and sterilized and used directly for injection for treating anemia.

Instant claims require a water soluble iron carbohydrate complex "obtainable" from an aqueous Fe (III) salt and an aqueous solution of the oxidation product of maltodextrin of various DE values (see claim 1 for complete details). The base claim 1 does not specify all the necessary oxidation conditions and what is meant by "oxidation product." It is the Examiner's position that the prior art ferric D-glucuronate is obtainable from oxidizing a maltodextrin of any DE value and reacting the oxidized product with a ferric salt, as claimed. U.S. Patent 5,831,043 is evidence that glucuronic acid is one potential oxidation product of maltodextrin (see Example 4 on column 7)[1]. The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[1] This is a permitted use of another reference in a 102 ground of rejection. U.S. Patent 5,831,042 is being cited to merely establish that the prior art glucuronate is obtainable from oxidation of maltodextrin.

Claims 1-8 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over HCAPLUS abstract 2003:135397 in view of the acknowledged prior art, Thaburet et al. and Dokic et al.

HCAPLUS abstract 2003:135397 discloses a method of making iron dextran (oxidized) as an iron supplement. The method involves:

> adding a sodium hypochlorite solution to a solution of dextran and oxidizing at 20-25°C for >12 hours;
>
> adjusting a ferric chloride solution to pH 1.5-2 and reacting it with the oxidized dextran at 30-35°C for 1-1.5 hours; and
>
> neutralizing with a NaOH solution to pH 7-7.5.

Applicant admits in the specification the following – use of iron carbohydrate complexes for treating or prophylactically treating iron deficiency anemia is known (page 1, lines 13-15). Iron dextran complexes as well as complexes based on pullulans are known for parenteral application; and other iron carbohydrate complexes are known for oral application (page 1, lines 18-23).

Thaburet et al. disclose oxidizing maltodextrin with TEMPO-NaBr-NaClO oxidizing system (page 22, first two full paragraphs starting from the left column; see also the entire article). pH 9.5 is disclosed to best achieve minimized depolymerization

of polysaccharides (page 28, right column, last paragraph). Commercial maltodextrins have DE of less than 20 (page 22, right column, second full paragraph)[2].

The article by Dokic et al. is cited to merely establish the well-known fact that maltodextrins have a DE value range of 2-20 and have wide applications of utility (page 435, first paragraph).

The prior art does not expressly disclose applicant's process of oxidizing maltodextrin and combining with an iron (III) salt to produce a water soluble iron carbohydrate complex, as claimed (see the claims for complete details). However, as admitted by applicant, iron carbohydrate complexes of many different types are known for providing physiological iron to subjects in need thereof. One particular well-established iron carbohydrate complex, iron dextran, has been taught to be modified by complexing ferric chloride with oxidized dextran (HCAPLUS abstract 2003:135397). Thus, one having ordinary skill in the art would have found it obvious to complex oxidation product of another physiologically acceptable carbohydrate, such as for example maltodextrin, with ferric chloride. Additional specific details of applicant's claims are addressed below.

Dextrose equivalent features: Maltodextrins typically have the feature of DE range 2-20. This is merely a recitation of a feature that is necessarily present in available maltodextrins.

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[2] 100 divided by a number greater than 5 means the DE is less than 20 (Thaburet et al., p. 22, right

Oxidation of maltodextrin with aqueous hypochlorite (with bromide) at a pH value within or at the alkaline range: This is a known process for oxidizing maltodextrins and other polysaccharides (Thaburet et al.; see also HCAPLUS abstract 2003:135397). TEMPO-NaBr-NaClO oxidizing system reads on the oxidizing system of the claims. pH value with the alkaline range is obvious from its benefit of reduced depolymerization. Motivation to use such oxidizing system arises from its ability to provide selective oxidation with low depolymerization at specific conditions (Thaburet et al.).

Reaction of iron (III) salt with oxidized maltodextrin is carried out 15°C to boiling point for 15 minutes to up to several hours: The method of the cited HCAPLUS abstract 2003:135397 teaches this step with oxidized dextran (30-35°C .for 1-1.5 hours) As noted above, using this method with another physiologically acceptable polysaccharide, maltodextrin, would have been obvious since iron carbohydrate complexes of many different types are known for providing physiological iron to subjects in need thereof.

Oxidized maltodextrin and iron (III) salt are mixed to form an aqueous solution having a pH value so low that no hydrolysis of iron (III) salt occurs, whereafter the pH is raised to 5-12 by addition of a base: The process of the cited HCAPLUS abstract 2003:135397 teaches adjusting a ferric chloride solution to pH 1.5-2 before reacting it with the oxidized dextran (substitution with oxidized maltodextrin has already been addressed), and then neutralizing the reaction mixture with 40% NaOH to pH 7-7.5.

---

column, second full paragraph).

This process reads on the applicant's claimed feature under discussion. With the ferric chloride at pH 1.5-2 and having to add 40% NaOH to neutralize to a neutral pH range, the reaction mixture is clearly at acidic pH range and the claimed low pH range is obtained.

Medicament, formulated for parenteral or oral application: Iron carbohydrate complexes are known medicaments for parenteral or oral applications. Given the various complexes of iron-carbohydrate derivatives already developed in the art, the claimed iron carbohydrate complex obtainable from reacting iron (III) salt such as ferric chloride with oxidation product of maltodextrin, as claimed, would have been obvious as a medicament, for parenteral or oral application.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

It is noted that HCAPLUS abstract 2003:135397 was made publicly available on February 24, 2003, which is before the International filing date but not before the foreign priority filing date of applicant's related applications. Since the foreign priority application is not in the English language and since applicant has not provided a verified translation thereof, HCAPLUS abstract 2003:135397 is applicable against the claims. If applicant submits a verified translation to perfect the claim of priority, applicant should

expect the Examiner to apply the original document which was abstracted, i.e. Chinese Patent Application publication CN 1353194, the publication date of which predates all of applicant's potential effective filing dates. The CN 1353194 document is not yet available to the Examiner so it has been ordered. Translation of this document is not seen to be necessary until applicant perfects the claim of priority.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim1-8 and 11-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 16 and 26-27

of copending Application No. 11/815,568 in view of HCAPLUS abstract 2003:135397, acknowledged prior art, Thaburet et al. and Dokic et al.

Claim 26 of the copending application sets forth a process of making an iron (III) maltodextrin complex comprising contacting maltodextrin having a DE of 5-37 with an aqueous hypochlorite solution having a pH of greater than 7 to form a reaction mixture and contacting the mixture with an aqueous iron (III) salt solution. Claims 13 and 16 of the copending application set forth a medicament comprising a complex of an oxidation product of at least one maltodextrin with iron (III) in various medication forms.

The secondary cited references have already been fully discussed above and the discussion there is incorporated herein by reference.

One having ordinary skill in the art would have been taught from the cited secondary references that the claimed process steps in the instant claims are known process steps for oxidizing carbohydrates, including dextrans, wherein carbohydrates and oxidized dextrans are also known for delivering iron to subjects in need thereof.

Therefore, one having ordinary skill in the art would have recognized the instant claimed invention as an obvious variation of the invention claimed in claims 13, 16 and 26-27 of the copending application.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Pak
Primary Examiner
Technology Center 1600